EXHIBIT-V

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EXHIBIT V

SUN PHARMACEUTICAL INDUSTRIES LTD.

Particulate Matter: (Limitation prescribed in the USP 26 <788>)

Of size ≥ 10 µm = Not more than 6000/vial
Of size ≥ 25 µm = Not more than 600/vial

Result and Test Procedure (Number of particles - Initial and after 3 and 6 months storage at 2°C - 8°C):

Take 10 vials and clean them exteriorly using jet of particle free water and dry. Open the vials using a vial opener in laminar airflow so as not to contaminate. Reconstitute each vial with 10 ml of particle free 0.9% sodium chloride injection. Transfer the contents in a particle free beaker and test the sample using "Light Obscuration Particle Count" by USP program. The results are depicted in the following Table II.

TABLE II

Particle Size (µm)	Average Number of particles per vial (As per USP 26 < 788 >)	PROPOSED GENERIC PRODUCT (Average Number of particles per vial)		
		Initial	After 3 months (Stored at 2°C - 8°C)	After 6 months (Stored at 2°C - 8°C)
10 µm	6000	206	3069	2431
25 µm	600	Nil	73	141

Result and Test Procedure (Number of particles in the proposed product after 6 months storage at 2°C – 8°C and reconstituted with saline):

Take one vial and clean it exteriorly using jet of particle free water, dry it. Open the vial using a vial opener in laminar airflow so as not to contaminate. Reconstitute the vial with 10 ml of saline (0.9 % sodium chloride injection), shake well. Further dilute the reconstituted solution with saline to make to the volume of 100 ml. Transfer the content in a particle free beaker and test the sample using "Light Obscuration Particle Count" by USP program. The results are depicted in the following Table III.

TABLE III

Particle Size (µm)	Average Number of particles per vial (As per USP 26 < 788 >)	PROPOSED GENERIC PRODUCT (Average Number of particles per vial)	
		Initial	At six months (stored at 2°C – 8°C)
10 µm	6000	440	3740
25 µm	600	30	20